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DEFENSE INTELLIGENCE AGENCY

WASHINGTON, D.C. 20340- 5100



S-64,027/PAG-TA

16 March 1994

MEMORANDUM FOR THE DIRECTOR, ENVIRONMENTAL AND LIFE SCIENCES, ODDR&E

SUBJECT: Protection of Human Subjects in Research (U)

Reference: OSD Memorandum, 17 February 1994, subject as above.

1. (S/NF) The Defense Intelligence Agency has determined that only one of its programs, Project STAR GATE, falls within the definition of human subject research. This research is conducted in two areas: in-house investigations conducted by DIA civilian personnel and external research activities conducted under DIA contract with the Science Applications International Corporation (SAIC).

2. (C/NF) Both the DIA and DOD General Counsels have determined that the STAR GATE Project constitutes experimentation on human subjects. As required by Procedure 13 of DOD Directive 5240.1-R, approval for project activities has been granted by the Deputy Secretary of Defense. All personnel involved with in-house investigations are required to sign a Statement of Consent form approved by the DIA General Counsel. Assignment to this project is voluntary, and employees may temporarily choose not to participate in the project at specific times or permanently discontinue participation at any time. There have been no demonstrated risks of permanent or temporary injury (including physical or psychological) to project personnel beyond risks to which they would ordinarily be exposed in their daily lives.

3. (C/NF) External research conducted by SAIC, as required by the current contract, is in full compliance with all applicable laws, federal regulations and DOD instructions, specifically:

- 45 CFR 46 Health and Human Services (HHS) Regulation, "Protection of Human Subjects";
- 10 U.S.C. Section 980, "Limitations on Use of Humans as Experimental Subjects";
- DOD Directive 3216.2 (2 January 1983), "Protection of Human Subjects in DOD-Supported Research";
- Federal Register Part II, (18 June 1991), "Federal Policy for the Protection of Human Subjects; Notices and Rules."

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4. (C/NF) Formal written assurance of compliance with the above has been provided by SAIC to DIA. In addition, all research plans/activities are constantly monitored by SAIC's Institutional Review Board to ensure that all applicable federal laws, directives, and regulations are fully and consistently implemented.

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5. (U) The administrative package governing the protection of human subjects in research should be forwarded to my point of contact Mr. [redacted] Technology Assessment and Support Activity (PAG-TA), Washington, DC 20340-5100. [redacted] can be contacted at [redacted]

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